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Hand Biomechanics Lab

K033112
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510(k) Summary

Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, CA 95825-6209

Contact: Timothy R. Stallings
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Prepared September 29, 2003

Name of Device:

Regulatory Classification:	Class II
Classification Name:	Component, Traction, Invasive [888.3040]
Common Name:	External Fixator System
Trade Name/ Proprietary Name:	WristJack ORIF System, Item No. CFD-347 WristJack ORIF System, non-sterile, Item No. CFD-347-NS
Performance Standards:	No performance standards exist for this device.

Predicate Device:

Agee WristJack Fracture Reduction System (sterile), Item No. CFD-147, K984442

Description of Device:

The WristJack ORIF System is an external fixation system used for reduction and fixation of distal radius fractures. The system includes an adjustable reduction/fixation frame (fixator), application instrumentation and skeletal fixation pins.

The fixator element has multiple adjustments to aid in fracture reduction and stabilization of distal radius fractures. The device and instrumentation are constructed of polyetherimide resin, carbon fiber, stainless steel, titanium and aluminum alloy. The fixation pins are constructed of implant grade 316 stainless steel per ASTM F138.

Intended Use:

Fracture reduction and external fixation for treatment of distal radius fractures.

Technological Characteristics Compared to Predicate Device:

The WristJack ORIF System is comparable to the predicate device with respect to application technique and adjustment function. The WristJack ORIF fixator has a beam element comprised of two carbon fiber rods compared to an injection molded Ultem component in the predicate device. The fixation pins and instrumentation are essentially identical to those included in the predicate device. The subject device is delivered to the customer in either sterile or non-sterile form. In the non-sterile model, the customer is responsible for sterilization before use. The predicate device is supplied sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Timothy R. Stallings
Manufacturing Manager
Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K033112
Trade/Device Name: WristJack ORIF System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: September 29, 2003
Received: September 30, 2003

Dear Mr. Stallings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Millerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033112

Device Name: WristJack ORIF System

Indications For Use:

Fracture reduction and external fixation for treatment of distal radius fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033112

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)